



## Notice of Intended Regulatory Action Agency Background Document

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| <b>Agency Name:</b>        | Department (Board) of Juvenile Justice   |
| <b>VAC Chapter Number:</b> | 170  |
| <b>Regulation Title:</b>   | <b>MINIMUM STANDARDS FOR RESEARCH INVOLVING HUMAN SUBJECTS OR RECORDS OF THE DEPARTMENT OF JUVENILE JUSTICE</b>  |
| <b>Action Title:</b>       | Establish a process for reviewing and approving research proposals involving human subjects, to effectuate the provisions of Chapter 5.1 (Section 32.1-162.16 et seq.) of Title 32.1 for human research. |
| <b>Date:</b>               | June 21, 2002  |

This information is required prior to the submission to the Registrar of Regulations of a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B). Please refer to Executive Order Twenty-Five (98) and Executive Order Fifty-Eight (99) for more information.

### Purpose

*Please describe the subject matter and intent of the planned regulation. This description should include a brief explanation of the need for and the goals of the new or amended regulation.*

The regulation establishes minimum standards for research on human subjects under the care of the Department of Juvenile Justice. The goals of the new regulation are to provide a fair and thorough review of proposals to conduct human research, including review by a specially established human research review committee, so as to protect the safety, rights and confidentiality of human subjects.

### Basis

*Please identify the state and/or federal source of legal authority to promulgate the contemplated regulation. The discussion of this authority should include a description of its scope and the*

*extent to which the authority is mandatory or discretionary. The correlation between the proposed regulatory action and the legal authority identified above should be explained. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided.*

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Code of Virginia Section 66-10.1 directs the Board of Juvenile Justice to promulgate regulations pursuant to the Administrative Process Act to effectuate the provisions of Chapter 5.1 (Section 32.1-162.16 et seq.) of Title 32.1 for human research to be conducted or authorized by the Department. Thus, the regulation is mandatory.

Code of Virginia Section 66-10 (6) gives the Board of Juvenile Justice the power and the duty “to promulgate such regulations as may be necessary to carry out the provisions of this title and other laws of the Commonwealth administered by the Director of the Department.”

## Substance

*Please detail any changes that would be implemented: this discussion should include a summary of the proposed regulatory action where a new regulation is being promulgated; where existing provisions of a regulation are being amended, the statement should explain how the existing regulation will be changed. The statement should set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of citizens. In addition, a statement delineating any potential issues that may need to be addressed as the regulation is developed shall be supplied.*

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The regulation requires that researchers using human subjects have appropriate academic or professional standing, and that the research conforms to applicable professional standards of ethics. There is specific guidance governing the confidentiality of subjects and records; requirements for obtaining the informed consent of subjects; and prohibitions of experimental medical, pharmaceutical or cosmetic research.

Procedural guidelines specify the form and content of research proposals; the review process, including review by a Human Research Review Committee when research will involve human subjects; and the requirements for formal approval by the Director and a written agreement between the researcher and the Department.

As required by law (Code of Virginia Section 66-10.1), the regulation requires the human research review committee to submit to the Governor, the General Assembly, the Board of Juvenile Justice and the Director at least annually a report on human research projects approved by the committee, and the status of such research, including any significant deviations from the proposals as approved.

There are provisions permitting the Department to make use of the research findings and to require a final report from the researcher.

## Alternatives

*Please describe, to the extent known, the specific alternatives to the proposal that have been considered or will be considered to meet the essential purpose of the action.*

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The Department has been operating under agency policies and procedures that establish essentially the same requirements as are set forth in the regulation. However, the Code of Virginia is clear that human research must be approved and conducted in conformity with regulations that are adopted pursuant to the Administrative Process Act, so the continued use of agency policy and procedure as guidance governing human research is not an acceptable alternative to the regulation.

## Family Impact Statement

*Please provide a preliminary analysis of the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

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The regulation will have no direct impact, either positively or negatively, on the institution of the family and family stability. The regulation does include provisions for parents to be involved in giving informed consent to human research involving a juvenile.